PATENT COOPERATION TREATY





PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 24991 WO	FOR FURTHER ACTION	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)				
International application No. PCT/EP2003/002969	International filing date (day/m 21 March 2003 (21.03		2)			
International Patent Classification (IPC) or n A61K 48/00	ational classification and IPC					
Applicant ORTHOGEN AG						
 This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36. This REPORT consists of a total of						
V Reasoned statement citations and explan	Contain de account sided					
VII Certain defects in the international application VIII Certain observations on the international application						
Date of submission of the demand Date of completion of this report						
18 July 2003 (18.07.2	2003)	23 March 2004 (23.03.2004)				
Name and mailing address of the IPEA/EP	Author	Authorized officer				
Facsimile No.		Celephone No.				



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International application No.

PCT/EP2003/002969

I. Basis of the report									
1.	With	regard to	the elements of the international application:*						
		the inte	rnational application as originally filed						
	$\overline{\boxtimes}$	the desc	cription:						
		pages	1-40	, as originally filed					
		pages		, filed with the demand					
		pages	, filed with the letter of						
	\square	the clair	ms:	j					
		pages		, as originally filed					
pages, as amended (together with any statement und									
		pages		, filed with the demand					
		pages		01 March 2004 (01.03.2004)					
	\boxtimes	the drav	wings:						
	VY	pages	1/11-11/11	, as originally filed					
		pages		, filed with the demand					
		pages	, filed with the letter of						
	\Box_{t}	he seane	ence listing part of the description:						
	ш.	pages		as originally filed					
		pages		, filed with the demand					
		pages	, filed with the letter of						
	the in These	With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which he international application was filed, unless otherwise indicated under this item. These elements were available or furnished to this Authority in the following language which is: the language of a translation furnished for the purposes of international search (under Rule 23.1(b)). the language of publication of the international application (under Rule 48.3(b)). the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3). With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:							
	Ц		ned in the international application in written form.						
	\square		ogether with the international application in computer readable form.						
	\vdash	furnished subsequently to this Authority in written form.							
	H	furnished subsequently to this Authority in computer readable form.							
	Ш		tatement that the subsequently furnished written sequence listing does not ational application as filed has been furnished.	go beyond the disclosure in the					
		The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.							
4.		The an	nendments have resulted in the cancellation of:						
			the description, pages						
			the claims, Nos.						
			the drawings, sheets/fig						
5.			port has been established as if (some of) the amendments had not been made, sin the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**	ce they have been considered to go					
*	in th	icement i is report 10.17).	sheets which have been furnished to the receiving Office in response to an invitate t as "originally filed" and are not annexed to this report since they do not	ion under Article 14 are referred to contain amendments (Rule 70.16					
** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.									

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V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement			
Novelty (N)	Claims	2-4,6-18,21-29,31-39	YES
	Claims	1-5,19-20,30	NO
Inventive step (IS)	Claims	4,6	YES
	Claims	1-3,5,7-39	NO
Industrial applicability (IA)	Claims	1-39 (see below)	_ YES
	Claims		NO

2. Citations and explanations

D1: US-A-5 399 346 (ANDERSON W FRENCH ET AL) 21 March

1995 (1995-03-21)

D2: US 2002/034495 A1 (ANDERSON W FRENCH ET AL) 21 March

2002 (2002-03-21)

D3: WO 01 75131 A (UNIV TECHNOLOGY CORP) 11 October 2001

(2001-10-11)

*D4: Molecular Biotechnology 5(3), 259-261 (1996)

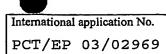
Matthews & Keating

*D5: BioTechniques 17(6), 1118-1125 (1994) Clarke et al.

- * These documents (not attached) are cited for the first time and were not mentioned in the international search report.
- See the citations in the international search report.
- The wording of claim 1 is not clear, since the claim relates to more than just a method in which whole blood (cells) is (are) transformed without prior separation of (blood) cells.

Claim 5, which is dependent on claim 1, makes this clear, namely that claim 1 should also encompass

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methods that are neither novel nor inventive, since they essentially cover only the isolation of blood cells and the subsequent transformation thereof (see page 2, second paragraph and D1 and D2: transfection of different blood cell fractions and types).

2. In this respect, page 6 makes clear in lines 14-17 the essence of the invention, namely that blood is transformed in such a manner that the blood cells to be transformed are not separated from the other blood components of the drawn blood beforehand, meaning that they are not fractioned.

Wording to this effect could redress the lack of clarity as to the scope of claim 1.

3. Methods for transforming cells using glass microbeads are known as one of the possible transformation processes, and therefore claims 19-20 and 30 lack novelty and claim 16 is not regarded as inventive (yeast: page 2, penultimate paragraph; mammalian cells: D4 and D5).

The blood cell transformation and the transformation of various types of blood cells are described in D1 and D2.

In light of the above, the transformation of blood cells using glass microbeads cannot be regarded as inventive.

Therefore, claims 1-3, 5, 7-15 and 17, 20-24 and 30-34 lack an inventive step.

4. Claims 25 and 35 lack clarity. What is the indicated

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drug kit comprised of?

Furthermore, claims 25 and 35 are not inventive with respect to D1 and D2, which describe transformed blood cells for therapy.

Consequently, claims 25-29 and 35-39 cannot be regarded as inventive.

5. It should be noted therefore that simply identifying a successful therapeutic application ("therapeutic application.:. with the systems described here"; page 35) without indicating more precise measurement results or data is not sufficient for demonstrating that an inventive step is involved.

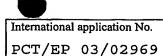
The applicant has substantially shown beyond a doubt that the transformation of whole blood using coated glass beads yields expression of the DNA used (cDNA for IL-1Ra) to form the corresponding IL-1 receptor antagonist protein IL-1ra, which is above the control values (figure 8, page 28; figure 9, page 34).

6. Claims 35-39 contain all of the essential features of claims 25-29. The same applies to claims 30-34 and 20-24.

In the interest of clarity and concision, the former group of claims in each case should not be independent claims, but rather should merely be worded as being dependent on the latter group of claims.

7. Claim 18 lacks clarity and should contain a





reference to a method which is described or to which reference is made in the claims.

8. The PCT Contracting States do not have uniform criteria for assessing the industrial applicability of present claim 17 in its present form.

Patentability may also depend on the wording of the claims. The EPO, for example, does not recognise the industrial applicability of claims to the medical use of a compound; it may, however, allow claims to the first medical application of a known compound or to the use of such a compound in the manufacture of a drug for a new medical application.